PUBLIC HEARING

BAR CODING - A REGULATORY INITIATIVE

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(202) 467-9200

P A N E L I S T S

FDA Panel (a.m.)

Margaret M. Dotzel, Esq., Moderator
Lester Crawford, D.V.M.
Theresa Mullin, Ph.D., Associate Commissioner, Planning and Evaluation, FDA
Steven Galson, M.D., M.P.H., Deputy Director, Center for Drug Evaluation and Research, FDA
Diane Maloney, Associate Director for Policy, Center for Biologics, FDA
David Feigal, J.D., Director, Center for Devices and Radiological Health, FDA
Erica L. Keys, Esq., Office of Chief Counsel, HHS

FDA Panel (p.m.)

Margaret M. Dotzel, Esq., Moderator
Steven Galson, M.D., M.P.H.
Diane Maloney, Associate Director for Policy, Center forBiologics Evaluation and Research, FDA
David Feigal, M.D.
Peter C. Beckerman, Esq., Office of Chief Counsel, HHS
Nancy C. Gieser, Ph.D., Office of Planning and Evaluation, FDA

A G E N D A

P R O C E E D I N G S

MS. DOTZEL: My name is Peggy Dotzel, and I'm the Associate Commissioner for Policy at the FDA. And I will be your moderator today. On behalf of the FDA, I'd like to welcome everyone here. And to get started, what I'd like to do is introduce you to the FDA panel.

Actually, first what I'd like to do -- I apologize -- is to thank Chuck Daniels -- he's the director of pharmacy services at the Nih Pharmacy Department -- for cosponsoring this meeting today.

And now I'd like to acquaint you with the FDA panel.

First we have our deputy commissioner, Dr. Lester Crawford. From our Center for Drugs, we have Dr. Steven Galson, who's the deputy director. From our Center for Devices, we have the center director, Dr. David Feigal.

Joining me from the Commissioner's office, we have Dr. Theresa Mullin, who is our associate commissioner for planning. From the Center for Biologics, we have Diane Maloney, who is the associate director for policy. And from our Office of Chief

Counsel, we have Erica Keys.

And now I'd like to turn the floor over to Dr. Crawford.

DR. CRAWFORD: Thank you very much, Peggy. It's a pleasure to be here, and it's a great thrill to see so many people come out on a stormy morning. And I hope that the storms are now over, both outside and inside.

It's my pleasure to talk about this morning how best to develop a regulation on barcode labeling for human drugs and biological products, and what should be the scope of such a rule. We will also begin to explore the feasibility of barcoding medical devices.

The issue before us goes to the heart of FDA's responsibility to the American people as the agency charged with the promotion and protection of public health. One of FDA's most exacting and critical duties is to make sure that drugs and medical devices that are used to treat patients are as safe as well as effective, and that their benefits outweigh their risks.

To meet this requirement, the pharmaceutical and device industries spend millions of dollars on conducting carefully designed and demanding clinical trials. And our agency uses still more resources, including state-of-the-art scientific expertise, to submit the results of these trials to a rigorous review.

The mutual goal is to make sure that each drug and device that reaches our market is as safe as it is humanly possible to make it. And we are confident that the products we approve meet that high standard.

Healthcare products that receive FDA's approval can be relied upon to develop important medical benefits. But they must be properly used. Unfortunately, that is not always the case.

Medication errors are a serious public health hazard, whether they are caused by a wrong diagnosis, misread prescription, mistaken dosage, incorrect device use, or poorly followed medication regimen. These errors can invalidate all of the expense, effort, and scientific erudition that had been invested into making these products safe and effective, with tragic

consequences for the patient.

Research cited by the National Academy of Sciences three years ago estimated that up to 100,000 patients die from preventable medical errors in hospitals alone. Medical errors are the eighth leading cause of death in the United States, or, as Secretary Thompson has put it, the equivalent of two passenger planes crashing every three days.

We believe that 30 to 50 percent of these deaths are associated with errors involving the use of FDA-regulated medical products, drugs, vaccines, blood and blood products, and medical devices.

In addition to the human cost, the economic cost of these errors is staggering. According to some studies, preventable morbidity and mortality related to drugs alone increases the nation's healthcare bill by more than $177 billion per year. Reducing this enormous toll, which exceeds the annual traffic fatalities on our highways, has been a high FDA priority for more than 20 years.

Over the years, our agency has addressed the hazard of medication errors by initiating many consumer

and health professional-oriented measures. These include: medication guides; drug- and disease-specific education programs; improved prescription and over-the-counter label formats; risk management initiatives; and a review of proposed product names to prevent their mixup with drugs already on the market.

Today we will discuss the pros and cons of yet another innovative measure that will help reduce preventable drug-related injuries and deaths, and that is the application of barcoding to human pharmaceutical products, biological products, and medical devices.

This is an important initiative that could bring great benefits to the public health because we know that barcoding can help ensure that the right patient gets the right drug and the right dose of it at the right time.

The use of barcoding in several hospitals has shown that the system can significantly diminish medication errors. For example, we have invited a representative of the Veterans Administration Hospital in Chicago, Illinois to tell us about their experience with the barcoding system that is estimated to have

prevented about 380,000 medication errors in a five-year period. And we all look very much forward to hearing that presentation.

One hospital in New Hampshire registered an 80 percent reduction in medication errors, and a medical center in Colorado reduced its medication rate [sic] by more than 70 percent. In both cases, as a result of their use of barcoding, these accomplishments were achieved. A 70 percent reduction in medication error rate is probably about as good as it can get.

The healthcare industry has projected that the use of barcoding across the medical supply chain could result in substantial annual savings. So we are very interested in your views, all of you here, on how a barcoding regulation should work, what it may cost to implement, and how it would affect patient safety.

Peggy Dotzel, FDA's associate commissioner for policy to my right, will be the moderator of today's discussions. In addition, we have other senior managers from our office and from FDA's Centers for Drugs, Biological Products, and Medical Devices. And we are all eager to hear your thoughts and suggestions

on this matter.

Once again, I want to thank you for attending this important meeting, and I hope you will find today's discussions useful and stimulating. And now I'll turn the proceedings back over to Ms. Dotzel. Thank you very much.

MS. DOTZEL: Thank you, Dr. Crawford.

Before we continue on with the agenda, I'd like to go over a few housekeeping details. First of all, we have noticed that a number of you have luggage with you, and if you'd like, they can store that luggage for you out at the registration desk so you don't have to keep it at your seats here.

Also, submissions to the docket can be made out at the registration desk. And the closing date for submissions to the docket is August 9th.

And then lastly, a transcript of today's meeting will be available, hopefully in about two weeks. And it will be available on our website.

You hopefully have also received out at the registration desk a copy of our agenda for today. As you can see from the agenda, we have a very full day.

We have some -- we have two panels scheduled to present, and then we have over 35 additional people who have registered to speak.

Because we have so many interested parties and because we have so much to accomplish, I am really going to ask the speakers to stick to the allotted time. We have a timer set up here so that you will see what -- you know, how your time is going. A yellow light will come on when there is a minute left. And then a red light will flash when your time is up.

And I apologize in advance if I have to start cutting people off, but like I said, we really have a lot to get through and I'd like to give everyone who has registered an opportunity to say their piece, and also I'd like for everyone to be able to go home for the weekend. So again, I really urge people to keep their eye on the clock so that we can keep things moving.

With that, I'd like to move on to our first agenda item. As Dr. Crawford noted, the VA hospital already has had experience with using a barcoding system. We have with us here today Kay Willis, who is

the chief of pharmacy at the VA Medical Center in Chicago, and she is going to present a video that provides an overview of the system that they are using in their hospital.

We are having some technical difficulties with the video and the sound is not very high, so I am really going to ask people to try to keep the background noise down while this video is being presented.

And with that, Kay?

MS. WILLIS: Okay. This is a tape from the Pinnacle Awards from the American Pharmaceutical Association. And it has been edited due to time constraints. So you can roll the tape.

(A videotape was played.)

MS. WILLIS: The medical literature clearly shows that medication errors have the potential to compromise patient safety and dramatically increase healthcare costs. The sources of medication errors are multi-disciplinary and often system-related. Within the Department of Veterans Affairs, a barcode medication administration system, or BCMA, has been

developed and implemented that addresses these issues.

The Department of Veterans Affairs is committed to improving patient safety through the use of barcodes and technology. VA pioneered the use of barcodes to improve the medication administration process at the VA Medical Center in Topeka, Kansas beginning in the early 1990s.

Data collected on reported medication errors from 1993, the last year before the barcode system was implemented in Topeka, compared to post-implementation data reported for 2001, show that Topeka VA was able to reduce its reported medication errors by an astounding 86.2 percent compared to the base year.

The medication error improvements by type of event include: 75.5 percent improvement in errors caused by the wrong medication being administered to a patient; 93.5 percent improvement in errors caused by the incorrect dose being administered to a patient; 87.4 percent improvement in wrong patient errors; and 70.3 percent improvement in errors caused when medications scheduled for administration were not given.

The Veterans Health Administration mandated the use of BCMA in June 2000 at all 173 medical centers in its network. Expansion of the BCMA software to include validation of IV medications has been added in Version 2. VHA has mandated that Version 2 be implemented by November 30, 2002.

One of the things VA is currently struggling with is a lack of barcodes on IV solution packaging. The national IV contract is coming to an end soon, and VHA will likely make barcoding a contract requirement for the next solicitation.

The National Center for Patient Safety was created as the patient safety arm of VHA. This office has worked to further improve the BCMA program within VA and facilitate the implementation of Version 2.

VHA pharmacy leadership is committed to patient safety and has made great strides in its endeavors. In addition to BCMA, VA's consolidated mail outpatient pharmacies, or CMOPs, have a lower error rate than other comparable facilities because of the use of barcodes and technology.

The drug is checked by a pharmacist via

screens that print an image of the drug that can easily be matched to the medication in the bottle. Drugs loaded into the automated equipment are barcoded for accuracy before they are loaded. Barcodes are also used in inventory management for ordering, receipt, and stocking within CMOPs.

VA's standardization of the appearance of multi-source generic products across the system by using committed use, multi-year contracts also promotes patient safety by alleviating patient confusion over differently appearing products.

VA recommends the implementation of uniform barcode standards down to the immediate unit of use package for legend drugs, over-the-counter drugs, vaccines, blood derivatives, and IV solutions.

Currently, VA pharmacies are required to repackage or relabel most unit of use products for inpatient use. Nationally, 14 percent of all preventable intercepted and non-intercepted adverse drug events result from dispensing errors alone. The incidence of dispensing errors increases with each product that requires repackaging.

Manufacturers' barcodes on unit of use products would eliminate the need for repackaging prior to dispensing, thereby reducing or eliminating the potential for error associated with repackaging.

Uniform barcode standards should include the national drug code, lot number, and expiration date. VA invites our industry partners to help in reducing medication errors and improving patient safety by embracing barcodes on all immediate unit of use packaging.

Once standards are reached, the national acquisition center can put some teeth into barcoding requirements in its solicitations. It is time for the pharmaceutical industry to continue its contribution to improving healthcare in the U.S. by voluntarily adopting uniform barcode standards and implementing the technology into all commercially-available products as soon as practical.

A medical student called me last week to discuss a possible medication error at another hospital. Two sound-alike medications were involved in the error. The student asked, "Mom, this wouldn't have

happened if we had BCMA."

Thank you.

MS. DOTZEL: Thank you very much, Kay.

And now we're going to have our first panel come up. The first panel this morning is a panel of representatives from various health professional organizations, and I'm going to ask them to come up to the stage now.

Okay. The way we're going to do this this morning is we're going to ask the different panel members to come up to the podium and give your presentations, and then after that we will have an opportunity for the FDA panel to ask you some questions. And if time permits, we will then also turn to the audience, and if the audience has any questions, we have mikes in each of the two aisles and you can come up and ask your questions.

First, from the American Hospital Association, we have John -- is John not here? All right.

Well, we will move on to Kasey Thompson, who is here from the American Society of Health System Pharmacists.

MR. THOMPSON: Good morning. My name is Kasey Thompson, and I am the director of the Center on Patient Safety of the American Society of Health System Pharmacists.

ASHP is the 30,000-member professional association that represents pharmacists who practice in hospitals, health maintenance organizations, long-term care facilities, home care agencies, and other components of healthcare systems. I am pleased to provide you with ASHP's views on the proposal to require that pharmaceutical manufacturers include barcoding on all drug products.

Before I address the question that the FDA asked in its announcement of this meeting, I would like to draw the FDA's attention to one point. Barcoding technology is entrenched throughout America in all types of venues -- grocery stores, department stores, libraries. It is something that everyone expects, and it is found everywhere except where it can do the greatest good, saving lives.

This is a high urgency public health and safety issue, and the time for action is now. ASHP has

long supported the use of barcoding technology to help prevent patient harm resulting from medication errors. ASHP adopted a policy in 2001 to urge the Food and Drug Administration to mandate that standardized machine-readable coding be placed on all manufacturers' single-unit drug packaging to, one, ensure the accuracy of medication administration; two, improve efficiencies within the medication use process; and three, improve overall public health and patient safety.

This is not a new concept. We know that the FDA has heard this recommendation numerous times. Finally, last December, the FDA announced in its semi-annual agenda that it would publish a proposed a rule requiring barcoding on drug and biological products. ASHP welcomed the FDA's announcement, and supports its stated purpose of reducing medication errors.

But again, time is slipping by. The most recent agency guess is that the proposed rule would be issued in November. ASHP has criticized the FDA in the past for dragging its feet on necessary changes in drug product packaging to ensure patient safety. The need

for this step is great, and the time for it is long overdue.

ASHP has the following specific comments related to the questions the FDA asked in the Federal Register notice announcing this July 26th public hearing.

Number one, which medical products should carry a barcode? What about blood products and vaccines?

Barcodes should be required on all pharmaceutical product packages down to the unit dose, single unit level. For barcoding to be effective in hospitals and health systems, products in unit dose packages must be made available by pharmaceutical manufacturers.

While we have received reports that some major manufacturers are about to make a public commitment to add barcodes to all packaging, including unit dose, some of our members report a disturbing trend whereby fewer and fewer manufacturers are producing drug products in unit dose packages, leaving repackaging up to individual hospitals.

This is a major concern. Not only does repackaging introduce new opportunities for mistakes to be made, it adds an additional cost which most average- to small-sized hospitals cannot afford. Repackaging also takes pharmacists away from their most important duty in hospitals, that is, managing patients' drug therapy.

There is evidence from over 40 years of research that proves that unit dose drug distribution systems improve patient safety by reducing medication errors, improving efficiency, and reducing costs.

The second question: What information should be contained in the barcode that is critical to reducing medical product errors?

Barcodes on drug products must contain the product's NDC number. This is the primary element that will be effective in meeting the expectation that health professionals will be able to verify that the patient is receiving the right drug at the right dose and at the right time.

Other elements that should be mandated include the product's lot number, which can identify products

for the purposes of drug recall; a database can link a specific lot to a drug given to a specific patient. Inclusion of the lot number would also be useful during public health crises where mass vaccinations or drug treatments need to be given.

The third data element, product's expiration date. Drugs are kept in numerous places throughout hospitals, and even with the diligent efforts of pharmacists and technicians to check for out-of-date drug products, it is impossible to verify and find all of them. Placing the expiration date on the barcode would tell the nurse at the patient's bedside if a drug is out of date before the patient gets the drug.

Third question: Should the proposed regulation adopt a specific barcode symbology?

Numerous symbologies exist for machine-readable coding of products, but some are receiving more attention than others because of their ability to fit on small package sizes and readability by most commercially-available scanners.

Common information systems standards need to be developed, either by FDA mandate in the proposed

regulations or through collaboration between industry, healthcare professionals, and technology experts, and consistently applied, for barcode systems to effectively interface with other hospital computer systems such as pharmacy, laboratory, blood bank, and billing systems, just to name a few.

Fourth question: Where on the package of drug products should the barcodes be placed?

The barcodes should appear on both the inner and outer wrap below the human-readable information. Barcodes on outer wraps are useful for inventory and distribution control. Barcodes on inner packaging are imperative at the time of drug administration.

Fifth question: What products already contain barcodes? Who uses the barcodes and how?

Reliable data does not exist on how many current products packaged in unit dose form contain barcodes, but it is well recognized that that number is few, especially for unit dose packages containing a standard barcode and the necessary data elements of lot, NDC, and expiration date.

The Department of Veterans Affairs, as we have

heard, is a national leader in using barcoding systems for scanning patient, nurse, and drugs at the bedside. A 1999 ASHP survey revealed that only 1.1 percent of U.S. hospitals used barcoding to scan patient, nurse, and drug at the bedside.

We are all aware, however, of mounting public pressures to improve patient safety. Once drug product packaging has barcodes, the pressure to improve patient safety by applying barcoding technology in institutional settings will escalate.

Institutions need incentives to use this important patient safety-enhancing technology. This can be achieved through an FDA requirement and commitment by manufacturers to do what is right for patients. Include barcodes on all product packages and make all product packages available in unit dose.

Sixth question: What is the expected rate of acceptance of machine-readable technologies in healthcare sectors? What are the benefits of using this technology in delivering healthcare services and other potential uses?

Practitioner demand for barcodes on

prescribing -- on prescription drug products and the capability of implementing such technology exists. More hospitals and health systems are in various stages of adopting machine-readable coding systems. What is needed is the product packaging that would allow its use.

The benefits of using machine-readable coding in healthcare sectors are twofold. First and foremost, a barcode system will improve patient safety by ensuring that the right patient gets the right dose of the right drug by the right route at the right time.

Second, a properly designed and implemented barcode system will enhance the efficiency and work flow of pharmacists, nurses, and other health professionals using the technology. A barcode system will be useful in bedside scanning, inventory control, billing, and laboratory systems.

Seventh question: When should a final rule requiring barcoding on drug products become effective?

We hope that there will be no more delays in an FDA requirement and commitment by manufacturers to do what's right for patients. Clearly, an early

effective date is necessary.

We're afraid, however, that from the continual hesitation to take action on this issue, we will not see anything from the FDA soon. If a proposed rule is not issued until this fall, even with a short public comment period it will probably be at least a year from now until we see the Agency's final rule.

How much time, then, will be given to manufacturers to make the necessary changes? A year or two? Market demand by end users -- hospitals, healthcare practitioners, wholesalers, and patients -- can help drive the speed at which drug manufacturers implement the new regulation.

ASHP appreciates the opportunity to comment to the FDA on this significant issue. We are ready to assist the agency in any way in developing its proposed and final regulations requiring barcoding on drug and biological products. Thank you.

MS. DOTZEL: Thank you, Kasey.

I'd next like to invite Dr. Joseph Cranston, who is here representing the American Medical Association.

DR. CRANSTON: Good morning. My name is Joseph Cranston. I'm a pharmacologist by training. And I currently serve as the director of science, research, and technology at the American Medical Association.

The AMA is the largest national professional association representing physicians and physicians in training, and I am speaking on behalf of the AMA at this meeting.

The AMA has had a longstanding commitment both to improve the quality of medical care delivered to patients by their physicians and to promote efforts that will improve patient safety. For example, the AMA established the National Patient Safety Foundation in 1997, and has participated in a number of initiatives on clinical quality improvement. The AMA also has been a partner and strong supporter of MedWatch, the FDA's adverse incident reporting program.

In 1999, the Institute of Medicine published its seminal report, "To Err Is Human," which raised public awareness to the important issue of patient safety. As discussed in that report, there is

considerable documentation in the medical literature that medication errors result in numerous patient injuries and deaths. This situation is unacceptable, and efforts must be made to minimize medication errors.

Evidence suggests there are numerous causes of medication errors, and therefore a variety of approaches will be needed to address this problem. The implementation of new information technologies is an area that offers enormous opportunities to improve patient safety. And the use of machine-readable coding, that is, barcoding, is one such technology.

The incorporation of scannable barcodes in a standardized format on all medication packages and containers should help ensure that the right drug and dose are administered to the correct patient. Thus, the AMA supports and encourages efforts to create and expeditiously implement a national barcoding system for prescription and over-the-counter medicine packaging in an effort to improve patient safety.

The extension of barcoding to other FDA-regulated products, such as blood products, vaccines, and certain medical devices, also appears to be a

reasonable and attainable goal.

The AMA has no official position on the specific elements that should be included in a proposed rule on barcoding. As a general comment, the AMA encourages the FDA to balance the need to put uniform barcode standards into place as soon as possible to reduce medication errors with the need not to stifle further innovation in barcode technology.

As a start, the AMA believes the June 2001 recommendations of the National Coordinating Council for Medication Error Reporting and Prevention, otherwise known as NCCMERP, entitled, "Preventing and Standardizing Barcoding on Medication Packaging, Reducing Errors, and Improving Care," should be given strong consideration by the FDA.

The NCCMERP recommendations were developed by a coalition of stakeholders, including representatives from medicine, pharmacy, nursing, consumers, risk managers, hospitals, accrediting bodies, the pharmaceutical industry, and government agencies, including the FDA.

In developing its recommendations, the council

conducted a thorough literature review and held a conference of invited experts in August 2000 to discuss needs assessment, current standards, equipment manufacturers, and cost implications. While the NCCMERP recommendations on barcodes focus on institutional settings such as hospitals, the recommendations may be applicable to other settings.

Now, the FDA is undoubtedly very familiar with the NCCMERP recommendations. However, the AMA would like to just briefly mention some of the key points for the record.

First, the FDA, the United States Pharmacopeia, the pharmaceutical industry, and other appropriate stakeholders should establish and implement uniform barcode standards, down to the immediate unit of use packaging, as defined in the U.S. PNF.

Two, the barcode should contain three data elements. A Uniform National Drug Code or NDC number should be the primary unique product identifier. Second, either the lot, control, or batch number should be one secondary identifier, and the expiration date as another secondary identifier.

Point number three, the three data elements -- the NDC, the lot number, and the expiration date -- should be uniformly ordered on the barcode using existing symbologies.

Fourth, there should only be one barcode on the label and it should have a standardized location.

And finally, the barcode should be included on the immediate container, labels of all commercially available prescription and OTC medications in any dosage form, on intermediate containers or cartons, and on shelf-keeping units.

As emphasized by NCCMERP, its recommendations are "a first step to the ultimate use of barcodes in the medication use process." Before hospitals, physicians, pharmacists, nurses, and especially patients can benefit optimally from this technology, barcodes must be uniformly present in a standardized format on unit of use packaging of all commercially available prescription and over-the-counter drug products.

In conclusion, the implementation of a national system for barcoding of commercially available

drug products and possibly other FDA-regulated products should help physicians and other health professionals to decrease the number of medication errors and the harm to patients that is associated with these errors. The AMA urges the FDA to quickly move forward with a proposed rule to require barcodes on drug product packaging. Thank you.

MS. DOTZEL: Thank you, Dr. Cranston.

Next, from the National Alliance of Health Information Technology, we have Tim Zoph.

MR. ZOPH: Thank you. Good morning. I am Tim Zoph. I'm vice president and chief information officer for Northwestern Memorial Hospital in Chicago, Illinois.

I'm here today on behalf of the new National Alliance for Health Information Technology, or known as the Alliance, a group of approximately 50 organizations representing providers, purchasers, manufacturers, and standard-setting organizations committed to "mobilize the field to address the fragmentation and lack of coordination in healthcare, improving quality and performance through standards-based information

systems."

We are pleased to have the opportunity to testify on an issue of critical importance for the healthcare industry and the people they serve, the barcoding of drug labels for unit of use pharmaceuticals.

Northwestern Memorial Hospital is a founding member of the Alliance and is committed to the first initiative of the Alliance, promoting the use of barcoding technology to create a safer, more efficient and effective patient care. I am here today to present the consensus recommendations of the Alliance to the FDA for their consideration as they develop a rule for the barcode labeling of human drug products.

By way of background, healthcare has trailed virtually every other industry in reaping the benefits of information technology advances, at least in part due to, one, a lack of consistent and uniform standards and protocols; two, its dependence on multiple scientific disciplines and medical specialities, each with its attendant technical requirements and demands.

As a result, the healthcare environment is

extremely fragmented, with isolated systems and databases. To improve the situation, the industry must begin to approach this more strategically.

The Institute of Medicine report, "Crossing the Quality Chasm," calls for "a national consensus on comprehensive standards for the definition, collection, coding, and exchange of clinical data." In comparison to other industries, healthcare has been slow to achieve this consensus. As a result, there has been an apparent failure to leverage even their limited investment in information technology aimed at improving patient outcomes and operational efficiency.

There are multiple causes for this failure, but one important cause is the absence of a standardized barcode on the label of unit of use pharmaceutical packaging. Only approximately 35 percent of all drugs administered at the bedside contain a barcode, which when used in conjunction with decision support tools, could dramatically reduce the incidence of medication errors.

The Alliance recognizes that the implementation of barcodes on unit of use medication

packaging is only the first vital step in realizing the promise of barcode technology in making our healthcare system safer. A set of recommendations for the National Coordinating Council for Medical Error Reporting and Prevention already exists and is a good starting point for discussion of barcoded labeling standards.

The Alliance reviewed these standards, and building upon them offers the following recommendations in response to the FDA's questions.

Firstly, for the proposed rule, the barcode label requirement, the Alliance supports the FDA's effort to propose a rule to require a barcode on the label of human drug products down to the unit of use packaging.

Our recommendations, based on the considerable expertise of our member organizations, can help the FDA to further define the details of a barcode implementation process for human drug products. Additionally, we desire to work with the FDA on further implementation of barcoding in healthcare to promote patient safety and protect patients from human and

system errors.

It is our desire today, in today's public hearing, it will aid the healthcare field and the FDA in achieving consensus on the prompt establishment of regulations for barcode labeling on human drug products down to the unit of use level.

Drugs and biologicals: The Alliance supports the implementation of a requirement for barcoding for all commercially available prescription and nonprescription medications. The code must be included on the labels of all unit of use pharmaceutical packaging.

All dosage forms, including oral solids, oral liquids, injectables, inhalers, nasal sprays, topicals, and other forms of specialized drug product packaging should include a barcode on their label. In addition to unit of use packaging, intermediate containers and cartons and shelf-keeping units should also be labeled with a barcode.

Eventually, vaccines, blood, and blood products should have an FDA requirement for labeling with a standardized barcode. Currently, only blood has

a barcode, and even it is not mandatory. Barcodes for vaccines are currently under investigation by the CDC. The absence of barcodes in blood products and vaccines could raise safety issues, especially for the tracking of contaminated products.

The National Drug Code, as established by the FDA, should be the initial data element included in the barcode. This should be implemented as quickly as possible. Inclusion of the expiration date and lot number, especially to track recalled and out-of-date products, should be added to the barcode as soon as technically feasible.

These components can be phased in over a longer period of time. Working out the technical products related to the lot number and expiration date should not delay the implementation of a barcoded label that, at minimum, identifies the drug, its strength, and manufacturer.

If the FDA proceeds with a rule including only the NDC number, the Alliance has the technical expertise and is willing to work with the FDA to identify solutions and time frames for implementation.

The choice of symbology for the barcode is a critical element of the proposed rule and should be governed by specific principles. The Alliance recommends that only existing symbologies utilized in healthcare with the capacity to include the NDC, lot number, and expiration date be used for the barcoded label.

Additionally, symbologies appropriate to pharmaceutical packaging size and capable of being scanned by existing and readily available commercial scanning technology should be selected. These principles would allow flexibility to pharmaceutical manufacturers, while providing for a level of standardization for the users of scanning devices, without significantly increasing their costs.

The placement of the barcode on packaging for human drug products should be in a position where the typical user of a scanning device can reliably and consistently scan it. The printing quality of the barcode should be at a C or better ANSI standard. There should only be one unique barcode for a unit of use package.

Hospitals have employed barcoding in their administration system or automated dispensing cabinets, but only after extensive repackaging of their pharmaceuticals has been undertaken. This lack of a preprinted barcode creates the attendant risk of introduction of new error through repackaging and relabeling into the medication process.

Medical devices: The Alliance, with its strong interest in patient safety, supports the eventual inclusion of certain medical devices in the barcode labeling recommendation. Because of the complexity of this issue, in selecting the devices to be covered and the information to be included, the Alliance feels strongly that the progress in labeling human drug products with barcodes should not be impeded by the issue related to medical devices.

The Alliance recommends that the FDA complete its proposed rule on human drug products and biologics, and then explore the feasibility of creating a barcode rule for selected medical devices.

Benefits and obstacles: The healthcare system will become safer with barcoding. Barcoding will

decrease medication errors. Barcoding will foster progress in developing interoperability of fragmented information systems. Barcoding will serve as a tracking tool for medication and device distribution.

The Alliance recognizes that while the cost to the manufacturer to place the barcode on a unit of use label is not insignificant, much larger expenditures will have to be made by the healthcare organizations to take full advantage of barcoded medication delivery.

However, healthcare has always had early adopters who, given the basic tools, have led the field to new levels of quality and service. We expect the same to happen once barcodes are widely available on human drug products.

Time frames: Today's hearings will raise many questions related to issuing a final rule requiring barcoding for human drug products. Realizing the NDC is the data element most easily incorporated in the barcode, we encourage the FDA to move quickly in establishing the requirement for barcoded labeling with at least the NDC. The Alliance offers its assistance to work with the FDA in identifying a specific date for

this requirement.

In conclusion, the Alliance would like to thank the FDA for this opportunity to address issues raised in proposing a rule on barcode labeling for human drug products and biologicals. We stand ready to work with the FDA, drawing on the expertise of our diverse member organizations, to resolve the outstanding issues related to the barcoding of drugs, biologicals, and devices.

We are committed to a consensus approach that places the patients and their safety above all interests. Only through such a broad-based and committed partnership will we achieve the promise of high quality patient care.

From a personal perspective, from a CIO who has the responsibility for the automation of the healthcare information processes at an institution that has patient safety at the core of its mission, we are now positioning our environment to take full advantage of barcoding technologies.

If this rule is adopted, we will support it. We will be technically and culturally ready to

implement barcoding to its fullest. We will benefit from its measurable results in safer care and operating efficiencies.

We see this barcoding rule as the capstone and last step in achieving a fully automated medication administration process that has our patients' interest and safety at its core. We firmly believe that safer care will be the ultimate result for our patients. Thank you.

MS. DOTZEL: Thank you, Tim.

Next we have Pamela Cipriano, who is here on behalf of the American Nurses Association.

MS. CIPRIANO: Thank you. I am Pam Cipriano, chief clinical officer at the University of Virginia Health System, and am representing the American Academy of Nursing and the American Organization of Nurse Executives, subsidiaries of the American Nurses Association and the American Hospital Association, respectively.

As front line healthcare workers, the nation's work force of 2.7 million registered nurses have made and continue to make substantial contributions to

reduce healthcare errors. The American Academy of Nursing and the American Organization of Nurse Executives embrace the development of point-of-care technologies that reduce medical errors and increase productivity, and appreciate the opportunity to discuss our view on the particular issue of barcode labeling for human drug products, biologicals, and devices.

A few weeks ago, the American Academy of Nursing, in conjunction with over 20 organizations, convened an interdisciplinary conference focused on using innovative technology to enhance patient care delivery. Nurses, pharmacists, physicians, hospital trustees, administrators, manufacturers, health policy analysts, architects, software engineers, and others gathered in Washington to begin harnessing the strength of technology in redesigning our practice environment and care delivery system in order to improve nurse retention and healthcare quality.

Conference participants supported the establishment of a system that, one, uses technology to improve productivity and safety through automation; two, improves medication administration processes; and

three, provides interactive, automatically recorded data at the point of care.

The opportunity for error reduction with barcode labeling for human drug products promises to be significant. Barcodes and other machine-readable codes are most effective when they are in a standard format, not yet consistently found in healthcare applications.

Barcoding is currently available to assist in the identification of patients, caregivers, specimens, medications, and equipment. It further facilitates automated documentation, record-keeping, billing, inventory tracking, and the study of near-misses and errors.

Ensuring appropriate medication administration is a complex process involving a series of interrelated decisions and actions among a variety of professionals. Errors can occur at any point in the process. Automated information and decision support systems have proven effective in reducing many types of medical errors. More specifically, barcode technology can minimize the variation in the medication cycle and decrease medication errors.

Use of barcoding automates the distribution, management, and control of medications. Such technology not only allows professional registered nurses to more accurately and efficiently administrator medications, but it also streamlines nursing's workload, thus allowing more time to be devoted to direct patient care activities.

Studies indicate that barcode labeling of drugs in acute care settings can prevent over 7,000 deaths a year and save nearly $5,000 per admission.

Further development and wide scale deployment of barcoding require the healthcare industry to address issues of standardization of code technology, compatibility, reliability, and affordability. Keys to the successful application of such technology include, one, ensuring end users are involved in the process from the beginning; two, creating integrated systems that do not require reentry or rekeying of data; and three, reducing the workload burden.

While the literature indicates that the mandated use of barcode labeling for human drug administration can provide substantial benefits to the

quality and safety of patient care, there are certain aspects in the implementation of this technology that require further consideration. And these are patient populations, standardization, compatibility, reliability, and financial considerations.

Children are a population at risk for errors. The IOM noted that a four-year prospective study found 350 medication errors resulting in injury among over 2,000 neonatal and intensive care admissions. Many pediatric doses are nonstandard and are prepared internally by the pharmacy. A mechanism for adding a barcode to institution-specific medications increases the cost of dose preparation and adds time.

Infant identification also presents challenges to barcoding for identification, given the tiny size of the limbs and the ID bands. Systems that link mother to baby may have barcode labeling for the mother but only manual identification for the infant. So the full benefit of the technology is not realized.

A second area for further consideration is the standardization of barcode terminology. While we are pleased with forward movement toward developed

appropriate standards for information exchange, the data and technology must be acceptable across various settings.

Nursing joins other organizations in support of the recommendations of the National Coordinating Council for Medication Error Reporting and Prevention that you have heard previously, which asks for the National Drug Code, NDC, lot, control, batch number, and expiration date at the unit of use package.

Barcoding of drugs should also be possible for nonstandard items at minimal cost to the dispensing pharmacy. This would include such preparations as ointments, lipids, TPN, manually prepackaged items, crash cart supplies, et cetera. Labeling of blood products should contain the donor, blood type, blood product, and attended patient, at a minimum.

Administration of a drug or therapy would also be guided or assisted with barcoding of the patient's identification data. Wristbands with barcoding can prevent any error by alerting the caregiver to a mismatch between the patient and the intended drug or treatment.

Implementation of barcodes for medication control often succeed in decreasing errors related to wrong dose, wrote time, omitted dose, and transcription or order entry. One Colorado hospital saw a drop of over 50 percent in different types of medication errors after implementation of their point-of-care information system for medication management.

Bedside medication verification products have been on the market as a complete system for two years. However, some of these systems are still very cumbersome. Nurses need a reliable, accurate, and rapid system that reduces workload and is more efficient or faster than a manual one.

One hospital discovered it had an eight-second delay in medication recognition and reconciliation with the patients' database. Until discovered through investigation of a medication error, this unacceptable delay was determined to be causing the nurses to circumvent the system. Nurses can be masterful at finding ways around systems when they don't work to their benefit. I must emphasize the importance of involving end users in the development and

implementation phase of this technology.

It is also desirable that manufacturers and suppliers of drugs and biological products provide 100 percent of products with barcoding. This will ease the workload of not only nurses but also pharmacists, also in short supply in the current and future workforce.

Implementing standards for barcoding will introduce some challenges for existing equipment. Systems need maximum flexibility to support both existing handheld scanner technology as well as other machine-readable formats.

Right now many organizations are challenged with having incompatible identification technologies. For example, a blood gas analyzer that is equipped to read the magnetic identification strip on the caregiver testing the specimen cannot read the patient identification system if it is in barcode format and if the machine has not been adapted for this scanning technology. Therefore, again, we don't have complete data capture.

The location of barcode labels on drugs needs to be adaptable to current technology, such a robots,

that pick medications and fill medication parts, again, dealing with the rewrap and overwrap issue. Transition to future two-dimensional codes will also require a bridge from existing to new technology. These codes are very promising, with high data density, redundant data, low contrast reading, and easy writing on conventional printers.

Further, the reliability of scanners to read the barcode is critical to the success of such technology. It has been found that some bar scanners cannot read curved surfaces. Since almost all identification bracelets are on a wrist, valuable time can be spent flattening out the identification band to allow the scanner to recognize it, often requiring as much time as would be spent administering a medication without benefit of technology.

Finally, we must raise the issue of affordability and financing of such technology. Clearly, the cost of implementation in practice settings will vary based on each institution and the structural changes required to manage the point-of-care systems.

Manufacturers and suppliers must share in the production of materials that respond to the mandate for safety and address workload burden. Collectively, we had a duty to reduce error and prevent avoidable adverse events.

Barcode labeling has proven beneficial for other advantages such as charge capture, billing, record-keeping, inventory tracking and control, and automated documentation for patient records and quality improvement review.

In conclusion, we applaud the FDA's efforts to improve patient safety and reduce the number of adverse drug events due to medication errors. Barcode labeling for human drug and biologic products is one means of applying simple technology to a broad spectrum of high-risk processes and realizing a significant safety impact. Thank you.

MS. DOTZEL: Thank you, Pamela. And then last, from the American Hospital Association, we have Dr. John Combes.

DR. COMBES: Good morning. My name is John Combes. I'm the senior medical advisor to the American

Hospital Association and the Hospital and Health System Association of Pennsylvania. I'm here today on behalf of AHA's 5,000 member hospitals, health systems, networks, and other healthcare providers.

We are very pleased to testify today on an issue that promises to improve patient safety, the barcoding of drugs, devices, and biologicals. I also represent AHA on and currently serve as chair of the National Coordinating Council on Medication Error Reduction and Prevention.

NCCMERP, as it is fondly known as, recently offered a series of recommendations on the implementation of uniform barcode standards, down to the unit of use level, for all pharmaceutical product packaging. The AHA, as a founding member of the council, supports those recommendations and desires to work with the Food and Drug Administration and other interested parties in the successful implementation in America's hospitals.

NCCMERP's recommendations for barcoding of the unit of use medication offers a good starting point for the development of regulations for labeling standards.

The recommendations identify the minimum data to be included in the barcode, labeling and format parameters, and suggest which packaging should be barcoded.

The council recommends the expeditious implementation of barcode labeling standards by the FDA in collaboration with the U.S. Pharmacopeia and the pharmaceutical industry. However, the council also recognized that the use of barcoding technology as a mechanism to improve medication safety should be implemented incrementally, with careful planning and giving thoughtful deliberation for cost, cultural, and implementation issues.

The AHA supports the FDA's efforts to require a barcode on the label of human drug products down to the unit of use packaging. Stakeholders still need to identify what products should be labeled with a barcode, what data should be included in the barcode, and what symbologies should be employed.

However, the general principle of including the barcode as an integral part of the label is supported by hospitals and health systems. We should

not wait until all the details are worked out for barcoding drugs, devices, and biologicals before instituting change.

Today's public meeting should help identify what can be done rapidly and what steps will require additional time. The FDA's regulation should codify what is doable now, and the FDA and healthcare industry together should develop a plan that will lead to the timely phase-in of barcodes on devices and other medical products for which we cannot implement barcoding immediately. The AHA stands ready to assist the FDA in these efforts.

Now I'll turn my attention to some of the questions raised by the FDA in their announcement of this meeting in the Federal Register.

The AHA supports the timely phased-in implementation of a requirement for barcode labeling beginning first with human drug products, both prescription and over-the-counter drugs. This approach allows for the development of bedside scanning capabilities in hospitals, which will enhance patient safety in the administration and dispensing of

medications.

Additionally, for those hospitals and health systems that already use bedside scanning, it will reduce the need for repackaging of medications, eliminating another potential source for medical error. Following the labeling of human drug products, the FDA should also mandate the barcode labeling of vaccine and blood products.

Adamant among the barcode should include the National Drug Code, the NDC number, as established by the FDA. Including the expiration date and lot number would also be beneficial and desirable, especially to track recalled products.

But there may be technical and cost issues that make this less feasible immediately. Resolving the technical problems related to the inclusion of the lot number and the expiration date, however, should not delay the implement of barcode label that, at a minimum, identifies the drug, its strength, and the manufacturer.

If the FDA proceeds with this rule, including only the NDC number, it should explore with the field

other ways for the lot number and expiration date to be available at the bedside.

It is important to recognize that hospitals have already made a significant investment in scanning technologies for clinical care and inventory control. Any symbology adopted by the FDA for barcodes should be compatible with current scanning devices used by healthcare organizations. Symbologies requiring optical scanning should not be mandated since this would require the wholesale replacement of current information systems at a significantly increased cost.

Barcodes are currently being used in hospitals for laboratory specimen identification, blood and blood products, inventory control, and automated dispensing cabinets. Some hospitals use barcodes in their medication administration systems, but only after extensive repackaging of their pharmaceuticals, which increases the possibility of medical error.

The major obstacle to the more widespread use of barcoding to improve patient safety is this lack of the preprinted barcode on the unit of use dose. Barcodes should be required on all packaging and

containers down to the level of use just prior to the administration of the product to a patient.

One of the most significant factors in reducing medication errors is the ability to identify the right drug and the right dose administered to the right patient. By including the barcode on the packaging used for the administration of the drug at the bedside, the right drug and the right dose can be easily identified.

The next step in a phased-in implementation of barcoding standards would be applying the technology to medical devices. The AHA supports the labeling of certain medical devices with machine-readable codes. This can improve patient safety by allowing the tracking of device failures, device-related infections, and unexpected outcomes related to the proper and improper uses of the device.

But not all medical devices need to be tracked in this way. Certain simple devices, such as bandages, tongue depressors, and crutches, may not require this type of labeling. Prior to the FDA proposing a rule for the labeling of devices with machine-readable

codes, studies should be undertaken to determine which devices labeled with barcodes would have the most impact on improving patient safety.

We should really look at our devices and stratify them according to the risk to the patient, and only those that pose the highest risk should be the ones that are barcoded. However, these studies should not delay the FDA from implementing a rule for the labeling of human drug products with barcodes.

A label for devices should include a unique identifier, which contains information on the specific manufacturer of the product and possibly the lot number. The FDA should establish a separate process, and perhaps a separate public meeting, to address the issues around the labeling of devices. Additionally, any labeling format should be consistent with what is established by the FDA's rule for the labeling of human drug products and biologicals.

The AHA encourages the FDA to have a planned process for the implementation of barcoding, beginning with drugs and blood products. At the same time, the FDA should start the process for identifying what

devices should be barcoded and what information should be contained in those particular barcodes.

Medication errors are a critical concern for everyone involved in healthcare. We must build systems that make sure the right patient is getting the right medication at the right dose at the right time. Barcoding technology can greatly enhance patient safety by ensuring there is a realtime verification of the correct patient, medication, dose, and time.

And hospitals are committed to using the best available technology within their resource capacity to improve patient care and reduce medical errors. We must recognize that placing a barcode on the label of human drug products is only the first step in creating a safer medication delivery system. Hospitals must have information systems in place, complementary technology, and trained personnel to create a safer system.

To maximize patient safety and to take full advantage of the information available from using barcodes, such a patient alerts about dosage limits, drug/drug interactions, drug/food interactions, and

allergies, hospitals and health systems must make significant investments.

The incompatibility of current information systems is an obstacle and a disincentive in hospitals that would need to make significant investments to put such systems in place. Can compatible systems be created in hospitals? Is technology stable enough to endure over time? Are hospitals investing in technology that will be quickly obsolete? These incompatibilities and questions are a major source of the costs associated with the use of the unit of use barcode.

In addition, hospitals face other costs, such as staff training in the use of barcodes and scanning and bedside scanning, and repackaging and labeling of extemporaneous preparations.

Finally, to improve medication safety through point-of-care barcode scanning, hospitals will need to establish a radio frequency backbone inside the hospital so that wireless devices may be used, without which many of the efficiencies of barcoding are lost.

Recently the AHA convened multiple

stakeholders interested in standardizing healthcare information technology. And you heard earlier from Tim Zoph from the National Alliance of Health Information Technology. I have the latest numbers. We are now over 60 organizations, representing providers, purchasers, manufacturers, and standard-setting entities.

The Alliance mission is to mobilize the field to address the fragmentation and lack of coordination in healthcare, improving quality and performance through standards-based information systems. The Alliance's first initiative is to promote the use of barcoding in creating a more efficient and effective system of healthcare.

The AHA has demonstrated its commitment of working with all stakeholders on this very important issue by being involved with the Alliance and helping to create the Alliance. It is our desire to move forward with the FDA and other interested stakeholders, including pharmaceutical manufacturers, device manufacturers, group purchasing organizations, to implement quickly this requirement for barcode labeling

of human drug products, and then to move as expeditiously as possible to the labeling of certain medical devices, blood, and other biologics.

I want to thank you for the opportunity for the AHA to speak before you. We are committed to improving patient safety. And with all your help, we can advance the science of patient safety and assure better outcomes for all our patients. Thank you very much.

MS. DOTZEL: Thank you, John.

Now I'd like to ask members of the FDA panel if they have any questions they'd like to ask our health professional panel.

Dr. Crawford?

DR. CRAWFORD: Yes. A clarification from Kasey Thompson. I believe you said approximately 1 percent of hospitals use barcoding. Is that correct?

MR. THOMPSON: Yes. An ASHP national survey conducted in 1999 --

VOICE: We can't hear you.

MR. THOMPSON: The microphone doesn't appear

to be on. An ASHP national survey conducted in 1999 of about 5- to 7,000 hospitals determined that only about 1.1 percent of those institutions currently use machine-readable coding technology to verify drug administration by the provider at the bedside.

DR. CRAWFORD: And is it your understanding that that is increasing, or remaining the same, or do you know?

MR. THOMPSON: My guess, and we'll have up-to-date data in the next few months, is that it's probably not increasing significantly because the product's not available. The fact that there's very few products available in unit dose packages with a barcode on it at this point in time doesn't provide a lot of incentive to hospitals at this point to purchase the technology.

I think once we get the technology available and the tools are there, meaning the unit dose packages with the barcode, you'll see the number of hospitals using the technology increase dramatically.

DR. CRAWFORD: And secondly, I'd like to ask a question of the entire panel. And that is is that what we are proposing is a regulation to cover the issue of

barcoding. And what we are about here is trying to figure out what should be included within that.

I take it you are all in favor of the regulatory approach?

MR. THOMPSON: Yes.

DR. CRAWFORD: Anyone not in favor?

(No response.)

DR. CRAWFORD: This is a first in my many years of -- I am going to retire at this point.

(Laughter)

DR. CRAWFORD: Dr. Combes, you did say that it should be phased in, and over about how long a period. One of the problems with phasing in is that, you know, we run the risk of losing momentum, and we believe this is very important from a public health point of view.

So I'd like for you to elaborate on that, if you wouldn't mind.

DR. COMBES: I think that after consultation with some of the pharmaceutical manufacturers, we should be able to get the barcode onto the label of unit of use packaging with at least the NDC number almost immediately. I mean, I think there really

shouldn't be much delay in doing that. In fact, we had an announcement from one of the major pharmaceutical companies the other day that they would be doing that in the future. And so I think we can get there.

There are some issues that we need to work on, technical issues about getting the lot and the expiration date. But I don't think those should take longer than a year to 18 months. I think the biggest problem is going to be with devices because we really do need to stratify the devices. Not all devices will need a universal product number or a barcode.

But there are certain devices which it would be very helpful to track when we have device failure, and particularly infections. I mean, we all are very familiar with the cases of the bronchoscopes up at Hopkins, and things of that nature, where you can go back and really hone down into what might be the problem. And that also gets into when we look at the sterilization of devices and the use of devices -- multiple uses of a single device.

DR. CRAWFORD: Thank you.

FDA PANELIST: I'd like to ask the panel a

question that you probably could each talk about for ten minutes. But just very, very briefly, what would you identify as the single biggest problem or impediment or concern about an FDA regulation in this area? The single biggest problem?

DR. COMBES: I'll take a shot at it. I guess if the regulation was overarching and didn't hear the concerns of the industry in terms of what was included in the regulation. But I think if we took a phased-in approach, there are things I think we can, as I just said, do right away, and are considerate of what technologies already exist in healthcare organizations.

I think that will work well. And I think if you work cooperatively with providers and manufacturers, we can get there. What we would hate to see is somebody say, we need to have data matrix codes or other kinds of codes on the label that we would have to change all our scanning devices and do a whole lot of retraining.

MR. THOMPSON: Well, I think you heard great agreement at this table that an FDA mandate is an absolute requirement at this point. It's been clear

for years and years that this wasn't going to be something that the industry was going to do on a voluntary basis.

So it really -- at this point in time, I think that the, you know, negative effects of an FDA mandate are very minimal. I mean, this needs to be done. There probably isn't a person in this room who hasn't experienced a medication error themselves or had a family member who has.

I mean, we're not talking about new technology here. We're not developing flying cars or alternative fuel sources. This is technology that's currently available now, and it's achievable. There's manufacturers testing it. They've said they can do it and include all three data elements. So it's there.

MS. CIPRIANO: I think one of the biggest concerns, however, is the implementation of a complete system. And probably the biggest fear is cost, particularly as we look at how broadly across our healthcare delivery system would these requirements be required -- in other words, nursing homes, the home care environment, outpatient environment where

typically we may have the same conditions existing in someone's own home that exist in some of these other low-intensity, low-risk environments.

So I think the biggest fear would be how sweeping would this requirement be; how quickly would the costs need to be incurred to have a system that not only provided identification of the drug in the dispensing end of the system, but also the match to the patient identification; and recording and looking for any kind of alerts in the system.

DR. CRANSTON: Yes. I think, from the AMA's perspective -- and we're going to be very flexible on this issue because we certainly are not the experts -- but I think that the benefits of a proposed rule or a final rule clearly outweigh the risks, I think.

But I think the problem side is that sometimes when FDA issues a rule, you know, kind of everything stops. And so, you know, the future innovation, ways to improve the system, you know, might be impeded.

So I think that you have to take that into consideration as you're putting together this rule so that we can get something out there quickly that's

useful that cause the hospitals to really want to take advantage of it, but at the same time, you know, there'll be means to improve the system in the future.

MR. ZOPH: Yes. I would just make the point, and you can tell from my testimony that the biggest challenge may be setting forth a rule and still having some unanswered questions related to medical devices and other evolving standards.

So I think that may be a challenge in terms of knowing that a rule may come forward and there is more work to be done. However, I believe that is absolutely the right thing to do.

FDA PANELIST: Much of the emphasis has been on the importance of these systems in hospitals. But an issue that's come up from time to time with recalls has been the changing practice of pharmacy. At one time in some states, it was required for pharmacists to write lot numbers on prescriptions and to track that. But as I understand it, most states have dropped that.

Would anyone care to update on the role that you see for barcoding in prescription drug containers given to the patient in an outpatient setting for

medications at the home? Is this something also that is something that should have benefits, or is this just a nice to have thing which shouldn't be required?

MR. THOMPSON: Well, I think something that's very clear in our interest here, and I think in the interest of patients, is that all pharmaceutical products contain a barcode. And, you know, we emphasize that that go all the way down to the single unit unit dose package.

We need to be very careful in some of the nomenclature on this as well. We're using unit of use and unit dose somewhat interchangeably. They're not. I won't get into the details of that.

But a single unit unit dose package is a package that contains a single drug in one individual package. A unit of use package is, for example, something like a package of oral contraceptives or a Medrol dose pack that has a specified series of doses. But you can look at the USP on that one. I won't get into a lot of detail.

But the key point here is the manufacturers be required to place barcodes on all pharmaceutical

product packages.

FDA PANELIST: But I guess my question is, would that extend to when the pharmacist, outpatient pharmacist, prints a label for that little amber-colored plastic bottle you take home? Does that barcode go on that for future reference as well? Do the pharmacists now track lot numbers to patients in the outpatient setting as well, or do you see this largely as an initiative that is primarily needed in the inpatient?

MS. CIPRIANO: I believe it needs to be extended to outpatient. What we find is that there are already -- up to 70 percent of patients never take their drugs correctly. So the barcodes aren't going to help with that part of the problem.

But I think if we're absolutely certain that we've done the correct identification, and then if a patient comes in and we are trying to track back any problems with those medications, or if we have recalls just like we record -- we do record lot numbers for samples of drugs that are dispensed in outpatient clinics and things like that. I think the more

information that is available, if there is any untoward effect, the better our management of those medications.

DR. COMBES: Actually, this issue came up in some discussions we were having several weeks ago. And we all kind of sat around and said, well, we didn't see how a patient would benefit in their home with a barcode on their medication label.

And somebody said, given how technology has advanced so rapidly in this area, particularly with handheld devices, one could imagine that a patient would maintain their own individual medication administration record at home, particularly patients who have complex drug regimens, and could actually, with the use of a PDA, scan their medications to make sure that they're taking the right medication at the right time.

So I think it might be shortsighted of us to dismiss that these would have any application in the home setting. And I think, you know, this is America, where there's an opportunity if somebody will come up with a device and make it work. So I think we should

consider that as we go forward.

FDA PANELIST: The other application that occurs to me is that on refills, the patient brings the product back. The pharmacist could rescan the label, see if they're actually dispensing the same medicine before -- make sure you don't have a name lookalike-type problem.

MR. THOMPSON: Let me just make one more point to address your question about the capability and the usefulness in the ambulatory sector. It would be very useful, and you addressed the point of should be this on product labels, meaning the actual prescription file you get.

Well, actually, if the lot number and expiration date and NDC were contained in the barcode, it would scanned in the pharmacy and then populated into a database there in that pharmacy. So you'd be able to identify patient with product dispensed and, you know, know who you gave a certain lot number to.

So I'm not advocating for or against putting this on an actual prescription vial but, you know, you would be able to do that through technological means

that way.

And with vaccines now, it's currently a requirement, I think, federally that we record lot numbers and expiration dates for all vaccines that are given. So it would be useful there just to be able to scan a barcode on the product and have that populated database.

FDA PANELIST: I have a question. All the panel members think that all three elements of the barcode that we've asked about should be in there, and some have said that a staggered implementation or incremental approach would be good.

Ms. Cipriano and Mr. Thompson, you advocated all three pieces, but didn't say anything about how it should be done. Do you see value in getting something like the NDC code on there as soon as possible, as opposed to delay for all components?

MR. THOMPSON: Well, clearly, the NDC is the most important element that would identify the drug and the dose and, you know, the specific product. So clearly, that absolutely positively has to be in the product.

Now, my concern is that with lot number and expiration date, that we not just let this fall by the wayside and delay it for five or ten years. If a tiered approach is needed to do that to get the industry, you know, in gear to do that, then that is fine.

I do know that there are pharmaceutical companies out there now that are testing this and have told me in private conversation that it's achievable to include lot number and expiration date and print on a high-speed production line at this point in time.

Now, if there needs to be some kinks worked out in that, fine. But let's not take too long to actually implement that and require that.

MS. CIPRIANO: I would agree. I think we need to move forward so that we can begin to implement the use of at least the NDC, as has already been supported by FDA.

FDA PANELIST: I have a question for Mr. Combes -- or Dr. Combes. I apologize. You spoke about a staggered implementation, and suggested first drugs and then biologic -- or vaccines, at least, and

blood second.

And my question to you is, given that, for instance, in the blood area, there already is some barcoding going on, what would be your justification or rationale for waiting for that, for those products?

DR. COMBES: Again, I think it's so we don't lose focus on the human drug products. Because that is something that there really hasn't -- hospitals and other healthcare organizations haven't taken advantage of because they haven't had the barcode.

In blood, it's my understanding that there are recommended standards, but no required standards out there around it. And there is some concern about the technology or the symbologies that were used for blood. And that may need to be investigated in terms of which symbology to choose for blood and what are the data elements as you go through a mandate.

I think that's going to take you a longer period of time than it would be to say, let's have the NDC number in the barcode on the label by January 1st. I think there's a little bit more investigation that has to be done. There has to be a lot more work with

the blood suppliers on that issue. And there has to be a resolution of the issues around symbologies, from my understanding.

FDA PANELIST: And just to pick up on that, and this is, I guess, for the whole panel, what I'm hearing people talk about is a lot of support for use of the NDC. And I think, Dr. Combes, you're the only who has sort of just mentioned the difference between, you know, sort of what's happening with blood products and the others.

I don't know if the rest of you have thought about the use of the NDC for blood products, given what's currently happening in blood. I believe they're not using the NDC now, and yet do some barcoding.

And then finally, my last question is for Tim Zoph. You talked about the data 35 percent, if I understood right, of medicines at the bedside are barcoded?

MR. ZOPH: Yes. We --

FDA PANELIST: If you can just tell me. And then, you know, you can add to that. But who's doing that barcoding? Is it the hospital? Is it the

manufacturer?

MR. ZOPH: We have -- what our experience is, again, the data, our evaluation of that is approximately 35 percent today of unit of use medications come in with a barcode. We actually repackage about 1 percent.

One of the points I'd make on this, too, on the repackaging because I know that has come up, we looked at what it would take for us to repackage all those medications that don't come in with a unit of use barcode.

And if you look at the error rate introduction into the process, if we give 2-1/2 million doses a year, and even if we take a ten-step process, assuming we can hit, say, a 99.9 percent effectiveness, we're going to introduce 70 new errors a day just from repackaging. So that's one point that I would make.

The other observation I'd make is that our own experience is that because unit of use packaging is a small part of the pharmaceutical business, and you may hear about this from the manufacturers this afternoon, is that we're actually seeing some decrease in the

actual packaging of unit of use into our institutions. So it's not only the label, but it's also the packaging that's occurring.

FDA PANELIST: But I'm still not -- who is putting the barcoding on? The VA talked about they did the barcoding themselves -- I don't know if that was correct -- as opposed to is anyone else doing that?

MR. ZOPH: Yes. We have manufacturers who are putting barcodes.

FDA PANELIST: Manufacturers?

MR. ZOPH: Yes.

FDA PANELIST: And how are you using those barcodes?

MR. ZOPH: Well, that goes to the core of it, is that unless we get to the point where we have such a high volume of barcode where we can introduce it in a reliable way into the process, that barcoding doesn't really serve a purpose for us now because we have a smaller number of products coming in with a barcode. So therefore, we've got to get to a much higher penetration of those barcodes coming into the institution before we can introduce it in a reliable

and predictable process.

DR. COMBES: There's a lot of repackagers out there and distributors that will barcode medications, particularly when you have automated dispensing carts. Those are generally repackaged with a barcode on them so that you can take advantage of those carts. So that would be one example.

FDA PANELIST: Can I just another question, then? If they are repackaging and putting a barcode, is there some sort of standardization right now with regard to what is on those because? The NDC number? The expiration date? The lot number?

DR. COMBES: I think they all have the NDC number on them. But beyond that, I'm not sure that there's any standardization, and it would depend on the repackager and it would depend on the distributor that was doing it.

Many of them are done by vendors of those automated systems, who supply the -- will repackage the drugs for you as part of their contract with you to have that automated system within the hospital. So they really do it for the purposes of their own devices

rather than have a universal standard that everybody would follow.

FDA PANELIST: Just following up on that, I'm assuming, then, these various readers that the hospitals have can read all of these different barcodes that might be unstandardized?

DR. COMBES: It's a little confusing, to say the least. Clearly, there are two levels of scanners that you can be concerned about. One is to move into optical reading devices. Those are very, very expensive scanners. They read the data matrix codes, which you can get barcodes in.

Now, there are linear scanners now, particularly the latest generation of linear scanners, that can be programmed up to read composite code. So you could read a linear code and the composite that they have the lot number and the expiration date in it. So a lot of the RSS codes can be read by these.

Some of the older scanners can't do that, and they theoretically could be upgraded but there may be problems in upgrading them. But the point is, most of these scanners have maybe a four- to five-year half

life or full life, and they get replaced over time. And the current generation of scanners can read almost anything other than moving to the optical scanning level.

So in terms of symbologies, you can really program the scanners to read almost anything if you tell them what to read, or you tell them that's a potential being out there.

FDA PANELIST: Let's assume that the rule goes into effect or that the NDC code is on all products at the unit dose a year from now. How quickly would you expect hospitals and the hospital pharmacies and other healthcare providers to adopt or to purchase the technology, invest in the technology, to scan it and start actually reaping the benefits? What would be the time horizon after that that you would expect to see those kinds of benefits?

MR. ZOPH: I'd be happy to take this. I think one observation I have for you now is that hospitals are, as you know, working very aggressively to implement computerized order entry. And as the studies show, that's obviously a very high point of error in

the system.

I do think by getting a standard out there, it will allow the providers of information technology solutions to understand that there is a standard and begin to develop those solutions, get them integrated into their electronic medical records so that the -- you know, a very quick add-on phase or subsequent phase of that, then when the barcode is available, institutions can begin to adopt and implement it. There is a period of time for which you need to pull together the technology community behind a common standard.

And I think the other thing it allows us to address as well is that there's a lot of benefit from things other than the medication scanning at the bedside, things like specimen collection.

And those of us in hospitals that have been really trying to understand how many different devices and scanning devices do we need at the bedside, and so on and so forth, it allows us to begin to take a look at scanning technology as a more universal tool at the bedside, and begin to work with our vendor community to

say, we want one device. It needs to be able to read these scanning technologies, and begin to work importantly with the whole cultural point of care setting that says, you know what? We can deal with medications, laboratory specimens, other material products, and have more universal solutions.

So we would be working aggressively in the meantime, once a standard is announced, to make sure that the products begin to get in the development life cycle within the technology community so when it's available, early adopters in the industry will be able to take advantage of the technology.

MR. THOMPSON: I think if you combine the FDA mandate that manufacturers do this and include the necessary data elements, and assuming that manufacturers continue to produce an enhanced production of products in unit dose packages, and provide that incentive to hospitals and healthcare organizations, that you'll see them adopt this fairly quickly.

Now, let's move out and look and see the demand for patients and the marketplace out there.

We've seen groups like leapfrog, say, you know, implement CPOE. They haven't said barcoding yet. But there'll be incredible market pressures out there by patients and others and private sector initiatives to tell hospitals to do this.

I mean, this is important in enhancing patient safety. But we've got to have the product available, and it has to have a barcode on the product package.

DR. COMBES: One of the by-products of having the rule, and I think this is why we're most interested in having the rule, is it will bring to our awareness our inability to get our hospital systems to communicate to one another.

The barcode will be only of an advantage if we can have patient information systems, laboratory systems, decision support systems, and other systems all linked together so that we can leverage the barcode to really make sure it's the right drug to the right person at the right time with no contraintroductions and no incompatibilities.

And that is only going to happen -- that is the long-haul process. That's only going to happen

when we start to develop more universal standards about how we use information technology in healthcare in the first place.

So I think, by the FDA taking this step, you can really push forward the industry in really seriously looking at how to capitalize off the advancements in information technology.

We heretofore have not done that, and I think this will help us. Because as Kasey said, there's going to be a tremendous amount of public pressure when they see the barcode on the label: Why are you not using it? And we will have to turn around to the people we work with and say, how come we can't use it in an effective way? We need to sit down together and work on some standards on this.

MS. CIPRIANO: I want to just elaborate on what John just said. The biggest difficulty is not getting a scanner. It's not acquiring the barcoded drugs. It's not putting the barcodes on yourself. It is having that information then be used at the point of care.

And that's really where the cost issues come

in, and that's where the time delay is, that if there is a mandate, most organizations -- and if we are thinking primarily hospitals and locations where patients are at higher risk -- the lead times for those kinds of changes can be no less than two years.

It's not an issue of philosophy, of safety, of things like that. But the practicalities right now, in terms of planning for technology, where there's either absent any other technology or information technology or in trying to look at getting systems to communicate, is just extremely taxing both timewise and financially.

MS. DOTZEL: I have two questions. One's a follow up question. I heard someone way -- I can't remember now if it was Tim or Kasey -- that right now manufacturers are not making a lot -- and I don't know whether the proper term is unit of use or unit dose, the individually packaged products that you oftentimes see in the hospital setting.

And my question is, to the extent that I think -- I would assume that type of packaging is more expensive, and then you add barcoding to that type of

packaging, which makes it even more expensive, is there a concern on your part that we might be creating even greater disincentive for manufacturers to package that way?

MR. THOMPSON: That's a real concern that we have. One thing I mentioned when I was speaking was that the unit dose drug distribution system has very good science behind it that it improves patient safety. And fundamental to that system is having products in unit dose packages.

Now, you combine a barcode with that, and the ability to add that extra layer of safety and protection and assurance for that nurse at the bedside that's giving the personal the medication that they're giving the patient the right medication, with all the five rights and everything, you have very powerful patient safety improvement.

There's a real concern out there that you've pointed out that we don't want to see an adverse effect of a rule becoming an industry -- I'll say excuse not to produce products in unit dose packages. There's science behind the unit dose drug distribution system.

It's effective at improving patient safety, and hospitals need this.

Now, I don't know what the costs associated with doing that are. But my guess is that they're minimal compared to the impact on improving patient safety.

MR. ZOPH: I guess my follow-up on that would be that, again, we talked about the repackaging issue. If you look at what's the right thing to do, the time to do this is the time of manufacture that's the highest quality and safest place to do it.

And secondly, there are a lot of costs of adoption, which we've talked about. So if the manufacturing industry embraces this, the cost of embracing is then the unit of use at the hospital level employing the technology, training the people and so on.

So there are costs, but I think there are costs to the complete system. But again, the right point to do this with the highest quality, I believe, is at the point of manufacturer.

MS. DOTZEL: And then my second question is

that there's been a lot of discussion about three data elements in the barcode, the NDC number, the expiration date, and the lot number. Are there any other data elements that we should be considering?

DR. COMBES: No. I don't think so. And this is why I have a little concern about the expiration date and the lot number, that there might be another way to get at it.

I think if you look at a barcode as really not a very intelligent item -- it's really a pointing device, a pointing device to a database -- you really don't have to have too much in the barcode as long as you have the databases to back it up.

Now, what we're asking you to do is make that barcode a little bit more intelligent for this labeling purpose by having the NDC number in it, and then beyond that, to get the expiration date and the lot number. But there are -- other elements that you may need will come when we again integrate our systems in able to point that barcode at these other databases.

So I don't think the FDA needs to get that into the barcode to make it smarter. We should be able

to do that by, again, working with industry to get some standards about how we can point that barcode to all these different databases we have.

The problem is as you start putting too much information in the barcode, then the real estate on the label gets taken up by the barcode. Even with some of the reduced symbologies, you're not going to get the information in there.

So I think where we are, to get the three items in it, would be very, very good. If we can start with the NDC number, that would at least get us -- get the ball rolling.

FDA PANELIST: One question I have that the panel can comment, and perhaps some of the speakers later in the day that are going to address device issues. But often, with medical devices, the same labeling is used in multiple countries.

And part of my question is, first, if you have any comments on what's happening in Europe or other kinds of systems with these kinds of technologies. But the other pressure that comes up in the device area in using -- moving to the increased use of symbols, not

just barcodes but other types of symbols, is to actually decrease the amount of language on the label and develop standardized meaning for symbols, like symbols for expiration date and other types of symbols, in part because of the European Union requirement to have information in all 17 languages of the European Union on the label. And for small products, that gets to be quite challenging.

So it's kind of a general question. But the question is, do you have some comments about, you know, where you see the future of getting standardized elements? And if you have any comments on the international scene?

MR. THOMPSON: I'll just make an indirect comment. We've talked about staggered implementation of things. I would suggest hat the FDA stay very focused on writing a workable regulation to provide barcodes on all pharmaceutical product packages down to the unit dose level.

I think it would be fantastic one day if we had devices barcoded. But I think the greatest impact, the greatest area of impact, on improving patient

safety is on the pharmaceutical product package.

I can't speak with any expertise about any of the issues that are going on in Europe with devices. I mean, I've worked with device failures in healthcare. But, you know, by and large, let's stay focused on getting barcodes on pharmaceutical product packaging.

FDA PANELIST: Actually, my question extended to pharmaceuticals as well. To your knowledge, does Europe use barcoding or other kinds of systems in their pharmaceutical systems?

DR. COMBES: It's my understanding that they do not use the NDC, which would be a problem. They're using universal product number, and that would be a whole nother issue that I think we would open up.

I think we have -- the NDC is something that we have. It's pretty pure. And I think, again, it would be very helpful because hospitals use it. Others use it to recognize drugs. It's used for reimbursement purposes.

So I think that's the major difference between the European system and our system.

FDA PANELIST: At the practical level, what it

would get down to would also be things like importation rules, whether drugs could be imported if they didn't have barcodes, NDCs, things like that.

MS. DOTZEL: I think now I'd like to give people in the audience an opportunity to ask any questions of our panel members. We have microphones in each of the aisles. And so if anyone has anything, please step forward to the microphones.

AUDIENCE MEMBER: Can we make a comment or ask a question? Either?

MS. DOTZEL: Questions for the panel is what we're looking for now, please.

AUDIENCE MEMBER: Okay.

(Laughter)

MS. DOTZEL: And if you could identify yourself as you come to the mike, that would be great.

MR. BRODO: Hello. A question. I'd like to just explore with the panel for a moment the intersection between this proposed regulation and the Prescription Drug Marketing Act; specifically, comments around the tracking of promotional drug samples and the use of barcodes on those packages.

Oh, I am sorry. My name is Robert Brodo. I am sorry. LScan Technologies.

MS. CIPRIANO: Was your question basically, should they be barcoded as well?

MR. BRODO: Yes. Is it your recommendation, is it part of your proposal, to make sure that barcoding is extended to all drugs, including not only in use in the hospital in use to patients, but also promotional drug samples? And there's implication as that perhaps transcends the Prescription Drug Marketing Act.

MS. CIPRIANO: My simple answer would be yes, for a lot of reasons, again, because the need to control the use of samples and track who they've been given to and what happens is probably even more difficult in an outpatient setting.

And so, again, it enables us to be able to track what patient, you know, got the medication, and be able to then carefully -- be able to have the data, just as if you were dispensing another prescription.

DR. COMBES: My answer would be yes. But I think in some respects, we're making the next leap.

What we're asking the FDA to do here is to put the barcode on the label of all drugs, over-the-counter drugs -- we're asking over-the-counter drugs, prescription drugs. So it wouldn't matter if it was a sample. It wouldn't matter -- every unit dose would have a barcode on it, or any unit packaging would have a barcode on it.

How that's used is going to be a whole different issue. And I don't think we're asking the FDA to tell us how to use it. We're asking them to give us the tool so we can use it.

And so we may be looking to some point in the future where physicians will scan the samples they hand out in their office and keep a record of it in their hopefully electronic medical record in their office someday. I mean, that's -- who knows. I won't be alive to see that.

But again, that -- but you can't do that unless you have the barcode on there. So we're asking them to take the first step on that.

MR. BRODO: Thank you.

MR. RITTENBURG: I'm Jim Rittenburg with

Biocode. And I wanted to ask the panel if they've considered using the barcode to also be a tool for helping to prevent diversion and counterfeiting, or diverted and counterfeited products from entering into the distribution chain by individually license plating every item through the barcode that's put onto that item.

MR. THOMPSON: I don't know if I can answer your question perfectly. But I think a lot of that would be taken care of if the pharmaceutical manufacturer producing the product was also doing all the packaging, and including the data elements on the barcode.

I can't really go much deeper into that than that but to say yes, I think that would be useful for that purpose.

MR. RITTENBURG: Yes. Because the only additional comment I'd make is with the recent cases of counterfeiting that have occurred, in many cases it's been due to labels being copied, and any information on that would also be copied.

So if a barcode only had an NDC number or lot

number, that could be produced en masse and copied, whereas if it was individually identified for every item, it would be much more difficult for somebody to just copy labels off and shove it into the distribution chain.

MR. MAYBERRY: My name is Peter Mayberry. I'm with the Health Care Compliance Packaging Council. A follow-up on the European question and the question about, you know, other countries specific to pharmaceuticals.

Kasey, you made the dichotomy between unit of use and unit dose. In your experience, do many other countries -- are you aware of other countries which do dispense in unit dose as opposed to bulk distribution, which we rely on in this country?

MR. THOMPSON: That's a good question, and I don't have any science to back this up. But I was on a recent vacation to Vietnam, Singapore, and Tokyo, and just walked through community pharmacies in those countries, they primarily dispense product in unit dose and unit of use packaging. That was just an observational method I used. But it seemed very common

in Asia.

MR. MAYBERRY: That also relates back to the cost. I mean, if they can afford to do it over there, do you have any speculation on why we can't afford to do it here?

(Laughter)

DR. COMBES: Well, unit dosing for most pharmaceutical companies is not a big part of their -- for hospitals, at least, a big part of their product line. I mean, they're not dispensing a whole lot of unit doses.

However, over-the-counters are almost always in unit doses. So obviously, it makes sense in an over-the-counter product that you're dispensing -- any time you get a cold preparation, it's always in the unit dose blister pack.

So I'm not sure why the problem is, except that it hasn't been a big part of what they've been selling to hospitals in the past, and putting another burden on -- may have them shut down those lines, which we think are very, very important for patient safety reasons.